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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,470	12/03/2004	Aylwin Ng	007193-5	4015

36234 7590 05/17/2007
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EXAMINER	
YAO, LEI	
ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,470	NG ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1, 6, 7, 8-10, drawn to a method for determining the presence or risk of nasopharyngeal carcinoma (NPC) by levels of protein in NPC cells.

Group II, Claims 1, 3-5, 8-10, drawn to a method for determining the presence or risk of nasopharyngeal carcinoma (NPC) by expression of nucleic acid in NPC cells.

Group III, Claims 2, 3-5, 8-10, drawn to a method for determining the type of NPC by expression of a transcribed nucleic acid in NPC cells.

Group IV, Claims 2, 6, 7, 8-10, drawn to a method for determining the type of NPC by drawn to a method for determining the type of NPC by levels of a polypeptide in NPC cells.

Group V, Claims 11-15, 18-20, drawn to a method of creating an expression profile characteristic of NPC or particular type of NPC, wherein the expression product nucleic acid sequence.

Group VI, Claims 11, 12, 16-17, 18-20, drawn to a method of creating an expression profile characteristic of NPC or particular type of NPC, wherein the expression product is polypeptide.

Group VII, Claims 21-26, drawn to diagnostic agent or a kit for expression of RNA.

Group VIII, Claims 21-26, drawn to diagnostic agent or a kit for expression of protein.

Group IX, Claims 27-34, drawn to a method of treating an individual with or at risk from NPC comprising administering a demethylation agent in association with a second cancer treatment

Group X, Claims 35-42, drawn to a method of screening for substance capable of treating NPC in an individual or the cells over-expressing one or more gene.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of

manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as group I, II, VII and VIII do not related to s single general invention concept because the lack the same or corresponding special technical feature. The technical feature of group I is drawn to method for determining the presence or risk of nasopharyngeal carcinoma (NPC) by expression of a polypeptide listed in table I, which is shown by Hwang et al., (Annals of oncology, vol 13, page 1246-1251, 2002) to lack novelty or inventive step. Hwang et al teach a method of correlating the risk of recurrence with expression of p16 gene, an inhibitor of CDK4, listed in Table1 (entire document). Therefore, the invention Group I does not make a contribution over the prior art. Because the method is known in the art, the technical feature of the Group I is not a special technical feature, the unity of inventive products Group VII or VIII and inventive method, Group I or II, is lacking.

In addition, according to PCT rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the other groupings are directed to method of using but each group has different special technical feature not shared by the remaining groups. Group III or IV are directed to a method of determining the presence or risk of NPC by RNA or protein expression not shared by any of the remaining groups. Group V or VI is directed to a method of creating an RNA or protein expression profile not sheared by any of the remaining groups. Group IX is directed to method of treating an individual with or at risk from NPC comprising administering a demethylation not sheared by any of the remaining groups. Group X is directed to method of screening for substance capable of treating NPC or cells not sheared each other or by any of the remaining groups. Because each group has different special technical feature, each is not shared by remaining groups.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

In the event that applicant elects invention I-VI and IX, applicant is required under 35 U.S.C. 121 to elect ONE single disclosed species listed in Table I for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

It is note that for the claim language, one or more genes identified in table, for example, in claim 1, applicant could indicate which ONE more gene listed in the table is additionally elected for examination together with the originally elected species above. If applicant chooses to do so a structurally or functionally related gene should be elected for examination together with the originally elected species.

In the event that applicant elects group VII, VIII or X, applicant is required under 35 U.S.C. 121 to elect a single identified gene listed in Table 1 or H19 or CDKNIC for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 11-14 and 20-21 are generic.

The species are independent or distinct because they are structurally and functionally non-related proteins or genes. Prior art, which teaches one species, would not necessarily be applicable to the method of using another or all the species. Searching the all the species in the method together would impose serious search burden.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

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SHANON FOLEY
SUPERVISORY PATENT EXAMINER
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